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IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

FRANK YOUNG, Commissioner of Food and Drugs,
Petitioner,

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,
Respondents.

**On Writ Of Certiorari To
The United States Court of Appeals
For The District Of Columbia Circuit**

BRIEF OF AMERICAN FEED INDUSTRY ASSOCIATION AS AMICUS CURIAE IN SUPPORT OF PETITIONER

Of Counsel

LEE H. BOYD
VICE PRESIDENT
AMERICAN FEED INDUSTRY ASSOCIATION
1701 North Fort Myer Drive
Arlington, Virginia 22209
(703) 524-0810

Dated: February 7, 1986

DAVID F. WEEDA
(Counsel of Record)

KATHLEEN M. SANZO
OLSSON AND FRANK, P.C.
1029 Vermont Avenue, N.W.
Suite 400
Washington, D.C. 20005
(202) 789-1212

PRESS OF BYRON S. ADAMS, WASHINGTON, D.C. (202) 347-8203

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STATEMENT OF INTEREST OF THE AMICUS CURIAE

Amicus, the American Feed Industry Association (AFIA), submits this brief in support of the Petitioner Frank Young, Commissioner of Food and Drugs. Consent to file this brief has been obtained from counsel

for all parties and has been filed with the Clerk of this Court.

AFIA is the national trade association representing manufacturers and distributors of animal feeds, feed ingredients, and animal drugs. AFIA members include private companies and cooperatives and range from large corporations to small local establishments. They include manufacturers of animal feeds, producers of feed ingredients, manufacturers of animal drugs, and blenders and distributors of animal health products.

AFIA's members are among the largest purchasers of U.S. agricultural commodities, such as corn, which are used as ingredients in finished feed products. Accordingly, AFIA is greatly concerned that the raw ingredients purchased by its members to produce finished feeds and the resultant finished feeds are "safe" both as a matter of law and science. The issue of the proper regulation of environmental contaminants in food is important to the U.S. feed manufacturing industry because modern food technology has not devised a method to remove trace environmental contaminants contained in raw agricultural commodities.

The Court of Appeals decision below hinders AFIA's ability to obtain federal guidance from the U.S. Food and Drug Administration (FDA) to resolve the legal and scientific issues related to the safety of foods containing trace levels of environmental contaminants. Indeed, the decision below, if upheld, would render illegal both feed ingredients and finished feeds if either contains *any* level of a contaminant, *even if* the finished product is judged safe as a matter of science. The decision needlessly threatens to disrupt the orderly marketing of agricultural commodities, animal feeds, and, indeed, human food; needlessly because the decision is legally incorrect.

INDUSTRY RELIES ON ACTION LEVELS

Since 1972, FDA has publicly issued policy guidelines which specify the maximum levels of several environmental contaminants which would be permissible in food products without violating the food adulteration provision in the Federal Food, Drug, and Cosmetic Act (the Act) covering added poisonous and deleterious substances, Section 402(a) of the Act, 21 U.S.C. § 342(a).[1] These guidelines, customarily known as "action levels," represent the agency's opinion as to what level of contamination is necessary to prove in a federal court enforcement action that a violation of Section 402(a)(1) of the Act has occurred. In other words, FDA's action levels are used by the agency as enforcement guidelines for the application of the "may render it injurious to health" standard in Section 402(a)(1). Because action levels are based on "what may be injurious to health," they provide guidance and certainty to feed manufacturers as to those levels of contamination which are safe, as well as legal.

Feed manufacturers rely on FDA action levels since they provide reasonable assurances that if feed in-

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[1] 21 U.S.C. § 342(a)(1) provides:

> A food shall be deemed to be adulterated --
> (a)(1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health. . . .

gredients fall within the established limits, they, as well as the finished feeds containing these ingredients, are safe for consumption. Feed manufacturers also rely on FDA action levels with respect to finished feeds. If their ingredients are "safe," their finished feeds may move freely and legally in interstate commerce. Thus, FDA action levels provide a dual benefit of certainty as to the safety of feed products to the consumer and as to FDA enforcement intention. The Court of Appeals decision replaces this certainty with chaos.

In the present case, FDA in 1974 had established an across the board action level of 20 parts per billion (ppb) aflatoxin for food and feed ingredients. In 1980, due to adverse weather conditions conducive to aflatoxin growth, Virginia, North Carolina, and South Carolina petitioned FDA to set a separate action level of 100 ppb aflatoxin for corn to be used strictly as an ingredient in animal feed for mature, non-lactating livestock and poultry. FDA, based on sound scientific evidence, agreed to the 100 ppb action level for corn used for these limited purposes. Moreover, the proposed distribution plan ensured the corn would not be distributed for unsafe purposes. Once FDA agreed to this action level, both the states and feed manufacturing industry knew that this corn could be safely and legally distributed for the stated purposes.

THE COURT OF APPEALS DECISION BELOW INVALIDATED ACTION LEVELS

Respondents, two public interest groups and a consumer, initially brought this action in the United States District Court for the District of Columbia challenging the procedures by which FDA approved

three state-sponsored plans for the safe distribution of corn containing innocuous levels of an unavoidable environmental contaminant, aflatoxin, a mold byproduct. The Respondents asserted that since aflatoxin is an unavoidable poisonous or deleterious substance, Section 406 of the Act, 21 U.S.C. § 346,[2] requires FDA to set maximum permissible aflatoxin levels by means of formal tolerances rather than informally by means of action levels. The District Court properly granted summary judgment in favor of FDA, holding that the agency has inherent discretion in deciding whether to proceed either by informal action levels or by tolerances pursuant to the formal rulemaking

[2]Section 406 of the Act, 21 U.S.C. § 346, provides:

> Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402(a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

procedures set forth at Section 406 of the Act and at Section 701(e) of the Act, 21 U.S.C. § 371(e).[3]

The Court of Appeals reversed, concluding that:

> "[t]he FDA is required to issue regulations establishing tolerances in order for food containing unavoidable added poisonous or deleterious substances to be considered unadulterated for the purposes of 21 U.S.C. § 342(a)(1) and unsafe for the purposes of 21 U.S.C. § 342(a)(2)(A). . . ."[4]

This holding condemns, as a matter of law, any food which contains *de minimis* levels of a poisonous or deleterious substance regardless of whether the scientific evidence shows that level to pose a risk to health. As discussed below, this holding is contrary to this Court's decision in *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914) and totally disrupts the orderly marketing of food products throughout the United States.

PRACTICAL EFFECT OF COURT OF APPEALS DECISION

It is impossible under current U.S. agricultural practice to avoid the presence of small quantities of field contaminants in raw agricultural commodities. These contaminants cannot be completely removed in

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[3]Section 701(e) of the Act specifies those formal administrative procedures for establishing tolerances for foods. *See infra* note 5 at 7.

[4]Petitioner's Petition for A Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit at 15A (hereafter *Pet. App.*).

processing. Thus, the Court of Appeals decision renders virtually the entire food supply adulterated as a matter of law until such time, if ever, FDA establishes formal tolerances.[5] Since this "legal" rule established by the court below totally ignores scientific evidence as to safety, feed manufacturers are left without guidance as to whether the ingredients they purchase are safe. More importantly, the decision gives feed manufacturers the Hobson's choice of either rejecting all incoming ingredients, which may present no risk to health, or breaking the law by producing technically "adulterated" and illegal animal feeds

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[5]The Court of Appeals indicated most of the practical consequences can be alleviated through the establishment of formal tolerances. *Pet. App.*, note 5 at 8a. However, this statement ignores the practicality of the situation. First, as FDA has conceded, it lacks the administrative resources to establish all necessary tolerances quickly. *Pet. App.* at 7. Section 701(e) of the Act, 21 U.S.C. § 371(e), requires the issuance of a proposed tolerance, a comment period, the issuance of a "final" tolerance, upon the receipt of a valid objection the staying of the "final" tolerance, a formal evidentiary hearing, various levels of agency "initial" and final decisions, and then appeal through the federal court system. Secondly, even if FDA had the administrative resources, formal tolerances can take years to establish. For example, it took eleven years to establish the formal tolerance for polychlorinated biphenyls (PCBs) in food and paper packaging materials, 21 C.F.R. § 109.30, even though in that formal administrative proceeding, FDA was able to avoid a full trial-type hearing which could have added years to the process. In another case, it took FDA eleven years to promulgate a standard of identity for peanut butter, 21 C.F.R. § 164.150, through the formal administrative hearing mechanism, including prompt judicial review. *See generally*, Hamilton, *Rulemaking On A Record By The Food And Drug Administration*, 50 Tex. L. Rev. 1132 (1972) and Note, *FDA Rulemaking Hearings: A Way Out Of The Peanut Butter Quagmire*, 40 Geo. Wash. L. Rev. 726 (1972).

which are safe as a matter of science. Thus, the purchasing of ingredients and the distribution of finished feed products containing traces of environmental contaminants could very well subject the feed manufacturer to lawsuits by FDA, state governments, or customers.

Under the Court of Appeals decision, FDA would have virtually no burden of proof to establish adulteration and would only be required to demonstrate in a court action that: (1) a feed ingredient or a finished feed contained any amount of a particular environmental contaminant, and (2) there is no Section 406 tolerance in effect covering that unavoidable contaminant in or on that product. Because of the ubiquitous nature of innocuous trace contamination of agricultural commodities,[6] the decision below means FDA can successfully litigate against virtually any feed manufacturer or feed product. Thus, every shipment of a contaminated ingredient or finished feed product could result in seizure and condemnation of the product, Section 304 of the Act, 21 U.S.C. § 334; and could subject the feed manufacturer to an injunction, Section 302 of the Act, 21 U.S.C. § 332, and criminal penalties including incarceration and fines of up to $100,000 per shipment, Section 303 of the Act, 21 U.S.C. § 333, and 18 U.S.C. § 3623. Even assuming FDA reasonably exercises its enforcement discretion and does not recommend that a federal court action be brought unless the amount of the contaminant in the food renders the food (here animal

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[6]Other ubiquitous environmental contaminants covered by FDA action levels are cadmium, crotolaria seeds, lead, mercury, nitrosodimethylamine, paralytic shellfish toxin, and polybrominated biphenyls (PBBs). *See*, Food Drug Cosm. L. Rep. (CCH) ¶ 50285.

feed) adulterated under the "may be injurious to health" standard of Section 402(a)(1) of the Act, a state agency could independently bring an action under its state food and drug statute.[7]

Feed manufacturers may be exposed to lawsuits by customers. Such a suit may be brought for breach of warranty since the product would be "illegal" if it contained any level of a contaminant. Alternatively, since a violation of a public health statute is negligence *per se* under many state laws and state court decisions,[8] the decision below may trigger court actions by farmers whose livestock or poultry develop health problems and who seek to blame the "illegal" feed without any scientific evidence demonstrating the contaminants actually harmed the animals.

Finally, AFIA is concerned that the Court of Appeals opinion will result in companies being forced to violate the law since it will be virtually impossible to obtain "pure" feed ingredients. AFIA's members are committed to producing safe and legal feed products. Any holding which questions the legality of this nation's entire food supply is suspect and, as will be shown below, is incorrect.

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[7]Most state food and drug laws parallel the federal Act, including the "may render injurious" prohibition of Section 402(a)(1). *See e.g.*, Cal. Health and Safety Code § 26520 (Deering 1984) and N.Y. Agric. and Mkt. Law § 200 (Consol. 1939).

[8]*See, Texsun Feed Yards, Inc. v. Ralston Purina Company*, 447 F.2d 660 (5th Cir. 1971); *Utah Cooperative Association v. Egbert-Haderlie Hog Farms*, 550 P.2d 196 (Utah 1976); *Kassab v. Central Soya*, 432 Pa. 217, 246 A.2d 848 (1968); *See also, Ezagui v. Dow Chemical Corp.*, 598 F.2d 721 (2nd Cir. 1979).

SUMMARY OF ARGUMENT

The Court of Appeals decision is wrong as a matter of statutory construction. Under Section 402(a)(1) of the Act, 21 U.S.C. § 342(a)(1), a food, including animal feed, is adulterated *only* if the quantity of the contaminant is present in an amount so that food containing the contaminant "may be injurious to health." By holding that the mere presence of any level of an unavoidable environmental contaminant renders the food adulterated, the Court of Appeals totally misconstrued this provision of the Act and, at the same time, overturned this Court's opinion in *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914). From this incorrect premise concerning Section 402(a)(1) of the Act, the Court of Appeals erred in concluding that the Section 406 requirement for an official and formal tolerance applied to this case. As this Court recognized in *Flemming v. Florida Citrus Exchange*, 358 U.S. 156 (1958), Section 402(a)(1) of the Act is the general test of adulteration and Section 406 comes into play *only* to sanction that which is prohibited by Section 402(a)(1). Since Section 402(a)(1), not Section 406, applies to the present case, the Court of Appeals incorrectly ruled that formal tolerances were required.

ARGUMENT

I. THE MERE PRESENCE OF AN UNAVOIDABLE ENVIRONMENTAL CONTAMINANT IN FOOD DOES NOT RENDER THE FOOD ADULTERATED UNDER SECTION 402(a)(1) OF THE ACT AS A MATTER OF LAW

In its opinion, the court below held that FDA must establish a tolerance in order for a food containing

unavoidable added poisonous or deleterious substances to be considered "unadulterated."[9] Since a tolerance is only required to sanction what would otherwise amount to adulteration, *Flemming v. Florida Citrus Exchange*, 358 U.S. 156 (1958), the court must have found that the very presence of any level of a poisonous or deleterious substance renders the product adulterated. This finding ignores the plain meaning of Section 402(a)(1), its legislative history, and this Court's opinion in *United States v. Lexington Mill and Elevator Co.*, 232 U.S. 399 (1914).

A. The Plain Language Of Section 402(a)(1) Requires A Showing That The Quantity Of Contaminant Poses A Health Risk

Section 402(a)(1) provides, in relevant part, that "a food shall be deemed adulterated. . .if it bears or contains any poisonous or deleterious substance *which may render it injurious to health. . . .*" (emphasis added). The Court of Appeals decision reads the statute without that final and qualifying phrase which requires FDA and the courts to look at the effect of the contaminant on health. Obviously, had Congress intended that the mere presence of an unavoidable poisonous or deleterious substance in food is sufficient for a finding of adulteration, it would not have added the qualifying final phrase.[10] Accordingly, under the

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[9] *Pet. App.* at 15a.

[10] For example, in the case of *avoidable* and unnecessary poisonous or deleterious substances, Congress in Section 406 of the Act declared foods containing such contaminants to be unsafe without qualification and adulterated under Section 402(a)(2)(A). Thus, there is no added requirement of showing a risk to health from the food containing the avoidable environmental contaminant. In the case before this Court, it is undisputed that aflatoxin is *unavoidable*. *Pet. App.* at 4a.

plain language of the statute, the question to be addressed and resolved is not so simple as whether the food contains any level of an environmental contaminant, but rather, the more difficult question of whether the *quantity* of the contaminant poses a risk to health.

B. The Legislative History Of Section 402(a)(1) Shows That Congress Did Not Intend To Establish A Per Se Rule

The "may render injurious to health" standard first appeared in Section 7 of the Pure Food and Drugs Act of 1906. (34 Stat. 769). When the statute was revised in 1938, Congress retained this standard mainly because this Court had reasonably construed this provision in the *Lexington Mill* case. *Flemming v. Florida Citrus Exchange*, 358 U.S. at 161.

The legislative history accompanying the 1906 Act makes clear Congress did not intend to render adulterated all foods containing any level of contamination. Mr. Heyburn, chairman of the committee reporting the bill on the Senate floor, stated:

> "As to the use of the term 'poisonous,' let me state that everything which contains poison is not poison. It depends on the quantity and the combination. A very large majority of the things consumed by the human family contain, under analysis, some kind of poison, but it depends on the combination, the chemical relation which it bears to the body in which it exists as to whether or not it is dangerous to take into the human system. . . ."

Lexington Mill, 232 U.S. at 412. Thus, it was never the Congressional intent to declare any food to be

adulterated for bearing unavoidable "poisons" in trace and innocuous amounts.

C. This Court Has Held That The Mere Presence Of A Poisonous Or Deleterious Substance, Without More, Does Not Constitute Adulteration Proscribed By The Act

In 1914, this Court was presented with the issue of whether Section 7 of the 1906 Act condemned the presence of any amount of a contaminant in food. There, a flour mill had treated its flour with a bleaching agent, nitrous oxide, which was considered a poisonous or deleterious substance. The federal government instituted legal proceedings to seize and condemn the flour bearing the nitrous oxide under Section 7 of the 1906 Act. In its instructions to the jury, the trial court "regarded the addition to the flour of any poisonous ingredient as an offense within the statute, no matter how small the quantity and whether the flour might or might not injure the health of the consumer." *Lexington Mill*, 232 U.S. at 408.

This Court reversed, holding the trial court erred in its jury instructions. According to this Court:

> "The act has placed upon the government the burden of establishing, in order to secure a verdict of condemnation under this statute, that the added poisonous or deleterious substances must be such as may render such article injurious to health. . . . If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the act."

Id. at 411.

This holding has been effectively reversed by the court below. If the decision is affirmed by this Court, the government need not show any risk to the public health from food containing innocuous levels of environmental contaminants; rather, it need merely show that the product contains a poisonous or deleterious substance. This is in direct contradiction to the plain language in Section 402(a)(1), its legislative history, and this Court's prior opinion in *Lexington Mill.*

II. SECTION 406 DOES NOT MANDATE FDA ESTABLISH A TOLERANCE FOR ALL POISONOUS OR DELETERIOUS SUBSTANCES

After erroneously concluding the mere presence of a poisonous substance, at even innocuous levels, renders a food adulterated, the court below proceeded to apply the Section 406 requirement of formal tolerances. Yet, as will be shown below, Section 406 simply does not apply.

A. Section 406 Does Not Apply To The Factual Situation Here

As the language of Section 406 of the Act[11] demonstrates, the provision addresses only two discreet situations. First, the addition of any poisonous or deleterious substance which is *unnecessary* and *avoidable* renders the product adulterated under Section 402(a)(2)(A). Second, if a formal tolerance for a *necessary* or *unavoidable* contaminant is established, a product containing levels of the contaminant in excess of the tolerance is also adulterated under Section 402(a)(2)(A). Section 406 does not cover poisonous or

[11]*See supra* note 2, p. 5 for the language of Section 406.

deleterious substances which are necessary or unavoidable and for which no tolerance is established. Indeed, since Section 406 does not apply to necessary or unavoidable substances, a food containing such a substance is not adulterated under Section 402(a)(2)(A); rather, Section 402(a)(1) applies together with its "may render injurious to health" standard.

In the instant proceeding, there is no dispute that aflatoxin is neither necessary nor avoidable. It is derived from an unavoidable field mold that produces a toxin on raw agricultural commodities. It is unnecessary but cannot be prevented or eliminated through good manufacturing practices. Accordingly, it does not fall within the first clause of Section 406. Likewise, it is agreed that *no* tolerance has been established for aflatoxin on corn and the second situation covered by Section 406 is not present here. In sum, the nature of aflatoxin contamination and its lack of utility in food products does not fall within the plain language of Section 406.

B. The Purpose Of Section 406 Tolerances Is To Sanction What Otherwise Would Be Adulteration Under Section 402(a)(1)

In the decision below, the Court of Appeals placed undue importance on the word "shall" in Section 406.[12] The court below indicated that this word imposed an affirmative obligation on FDA to establish tolerances in all cases.[13] However, all other federal

[12]The relevant language of this provision reads:

> "The Secretary shall promulgate regulations. . .to such extent as he finds necessary for the protection of the public health. . . ."

[13]*Pet. App.* at 6a.

Courts of Appeal which have considered this question have interpreted Section 406 differently: that no such affirmative obligation exists. *United States v. Anderson Seafoods, Inc.*, 622 F.2d 157 (5th Cir. 1980); *United States v. Boston Farm Center, Inc.*, 590 F.2d 149 (5th Cir. 1979); *cf. Certified Color Industry Committee v. Secretary of Health, Education and Welfare*, 236 F.2d 866 (2nd Cir. 1956).[14]

If Section 406 does not mandate tolerances in all cases, the question becomes when such a requirement comes into play. This question has been answered by this Court in *Flemming v. Florida Citrus Exchange*, 358 U.S. at 166. There, this Court stated:

> "The existence of a tolerance is specifically stated in 406(a) [currently 406] *only* to give sanction to what would otherwise amount to adulteration within the terms of 402(a)(1)."

Id. (Emphasis added). Accordingly, if the level of contamination does not violate the "may render injurious to health" standard of Section 402(a)(1), no tolerance is authorized or required.

In determining whether Section 402(a)(1) is violated, it is insufficient to show the mere presence of an environmental contaminant. Instead, FDA must

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[14]The court below attempted to distinguish these cases as being enforcement cases having nothing to do with whether FDA could affirmatively authorize a shipment of a product bearing innocuous levels of a contaminant. The court misconstrued the relevant import of the cases. These cases properly interpreted the word "shall" in Section 406 to mean there is no affirmative duty on the FDA to establish tolerances for any and all levels of a contaminant in food. As discussed below, the duty is triggered only in one specific instance.

show the contaminant is present at a level in a food which may render the food injurious to health. The determination as to that level of contamination which meets the Section 402(a)(1) standard necessarily implicates complex chemical, biological, and toxicological considerations. In such cases, it is appropriate for a court to give great deference to the agency with expertise in the area. *See, e.g., United States v. Boston Farm Center*, 590 F.2d 149 (5th Cir. 1979), *cf. Heckler v. Chaney*, 105 S. Ct. 1648 (1985); *United States v. Rutherford*, 442 U.S. 544 (1979).

FDA has used its expertise to make such determinations for various contaminants. The determinations as to those levels of unavoidable environmental contaminants which would be tantamount to a Section 402(a)(1) violation are called "action levels." FDA uses action levels as an enforcement guide specifying that level of contamination which the agency believes is necessary to establish a violation of Section 402(a)(1) of the Act in court. Action levels constitute the maximum safe and legal limit of an unavoidable or necessary contaminant. Thus, food bearing an amount of contaminants below FDA's action levels does not fall within the ambit of Section 406 since the food would not meet the "may render injurious standard" and does not violate Section 402(a)(1).

C. Since FDA Found No 402(a)(1) Violation, The Agency, By Modifying The Action Level, Acted In Compliance With The Federal Food, Drug, And Cosmetic Act

As discussed above, state governments petitioned FDA to approve the controlled and limited distribution of corn containing less than 100 ppb aflatoxin. The states submitted that the scientific evidence and the regulatory plan clearly established that such corn

could be safely used in animal feed for mature non-lactating livestock and poultry. Upon its review of the scientific evidence and the plan, FDA agreed that such use posed no risk to animals or to humans who consumed the edible tissue from the animals.

It is important to emphasize that FDA did not change its previous 20 ppb action level for the unrestricted use of corn. This general prohibition was expressly maintained in full force and effect by the agency. What FDA was requested to do was rule on the safety of a *specific* use under a *specific* regulatory program.

By making this determination, FDA found that this limited use did not violate § 402(a)(1) of the Act. Absent a § 402(a)(1) violation FDA was not mandated to establish a 406 tolerance and, in short, FDA acted in full compliance with the Federal Food, Drug, and Cosmetic Act.

CONCLUSION

For the foregoing reasons, *Amicus*, American Feed Industry Association, respectfully requests this Honorable Court to reverse the decision of the Court of Appeals.

Respectfully submitted,

DAVID F. WEEDA
(Counsel of Record)
KATHLEEN M. SANZO
OLSSON AND FRANK, P.C.
1029 Vermont Avenue, N.W.
Suite 400
Washington, D.C. 20005
(202) 789-1212

Of Counsel
LEE H. BOYD
VICE PRESIDENT
AMERICAN FEED INDUSTRY ASSOCIATION
1701 North Fort Myer Drive
Arlington, Virginia 22209
(703) 524-0810

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